

## **Amendments to the Claims:**

The following listing of claims will replace all prior versions, and listings, of claims in the application:

### **Listing of Claims:**

Claims 1 – 73 (canceled)

Claim 74 (currently amended): A self-microemulsifiable anhydrous base composition for use in the preparation of a spontaneously formed and thermodynamically stable microemulsion that can be used as an anesthetic composition, comprising:

- a) liquid propofol; and
- b) a nonionic surfactant consisting of polyoxyethylene (POE) having the structure of [POE(*n*)] sub~~m~~-R'- R; where POE (*n*) is a polyoxyethylene moiety of ~~-mer~~ number *n*, and having ~~m~~ of these POE functional groups attached to R'; where the value of *m* is one to three; where R' is a linking moiety selected from glyceryl, sorbitan, ester, amino, or ether functions; where R is a hydrophobic moiety consisting of saturated or unsaturated alkyl or alkylphenyl groups; and where the structure of the nonionic surfactant is further defined by a ratio of **A**, the total number of POE ~~-mer~~ units in the surfactant given by the product of ~~-mer~~ number *n* and total POE chain number *m* per molecule, to **B**, the number of carbons in the hydrophobic functional group R, the ratio of **A/B** being in the range of about 1 to 2 or in the range of about 0.7 to 4; and  
wherein the nonionic surfactant is included in the base composition in a concentration of about eight (8) parts or more of the nonionic surfactant to one (1) part of propofol, ~~and~~ with the base composition not containing any other surfactant other than said nonionic surfactant having said structure, and with the base composition not containing a co-solvent.

Claim 75 (previously presented): The base composition as in claim 74 in which the nonionic surfactant is selected from the group consisting of polyoxyethylene monoalkyl

ethers, polyoxyethylene alkylphenols, polyethylene glycol fatty acid monoesters, polyethylene glycol glycerol fatty acid esters, polyoxyethylene sorbitan fatty acid esters, and polyoxyethylene sterols.

Claim 76 (previously presented): The base composition of claim 74 in which the nonionic surfactant is selected from the group consisting of *PEG-15 monolaurate*, *PEG-20 monolaurate*, *PEG-32 monolaurate*, *PEG-48 monolaurate*, *PEG-13 monooleate*, *PEG-15 monooleate*, *PEG-20 monooleate*, *PEG-32 monooleate*, *PEG-72 monooleate*, *PEG-15 monostearate*, *PEG-660 12-hydroxystearate*, *PEG-23 monostearate*, *PEG-40 monostearate*, *PEG-72 monostearate*, *PEG-20 glyceryl laurate*, *PEG-30 glyceryl laurate*, *PEG-20 glyceryl stearate*, *PEG-20 glyceryl oleate*, *PEG-30 glyceryl monooleate*, *PEG-30 glyceryl monolaurate*, *PEG-40 glyceryl monolaurate*, *PEG-20 sorbitan monooleate*, *PEG-20 sorbitan monolaurate*, *PEG-20 sorbitan monopalmitate*, and *PEG-20 sorbitan stearate*, *PEG-40 sorbitan monooleate*, *PEG-80 sorbitan monolaurate*, *POE-23 lauryl ether*, *POE-20 oleyl ether*, *PEG-30-60 nonyl phenol series*, *PEG-30-55 octyl phenol series*, and mixtures thereof.

Claim 77 (canceled)

Claim 78 (previously presented): The base composition of claim 74 in which the base composition is homogeneous.

Claim 79 (previously presented): The base composition of claim 74 in which the base composition is optically transparent.

Claim 80 (withdrawn-currently amended): The base composition of claim 74 that also comprises a physiologic carrier liquid that is isotonic to blood, thereby forming the microemulsion. ~~An intravenously injectable microemulsion for use as an anesthetic composition, comprising:~~

- ~~a) the base composition of claim 74; and~~
- ~~b) a physiologic carrier liquid which is isotonic to blood.~~

Claim 81 (withdrawn): The microemulsion of claim 80 in which the microemulsion is optically transparent.

Claim 82 (withdrawn): The microemulsion of claim 80 in which the concentration of the propofol is included in the microemulsion in an amount of up to about 1% by weight of the propofol to the volume of the microemulsion.

Claim 83 (withdrawn): The microemulsion of claim 80 in which the concentration of the propofol is included in the microemulsion in an amount of up to about 4% by weight of the propofol to the volume of the microemulsion.

Claim 84 (currently amended): A self-microemulsifiable anhydrous base composition for use in the preparation of a spontaneously formed and thermodynamically stable microemulsion that can be used as an anesthetic composition, comprising:

- a) liquid propofol;
- b) a nonionic surfactant consisting of polyoxyethylene (POE) having the structure of [POE(*n*)] sub $m$ -R'-R; where POE (*n*) is a polyoxyethylene moiety of *-mer* number *n*, and having *m* of these POE functional groups attached to R'; where the value of *m* is one to three; where R' is a linking moiety selected from glyceryl, sorbitan, ester, amino, or ether functions; where R is a hydrophobic moiety consisting of saturated or unsaturated alkyl or alkylphenyl groups; and where the structure of the nonionic surfactant is further defined by a ratio of **A**, the total number of POE *-mer* units in the surfactant given by the product of *-mer* number *n* and total POE chain number *m* per molecule, to **B**, the number of carbons in the hydrophobic functional group R, the ratio of **A/B** being in the range of about 1 to 2 or in the range of about 0.7 to 4, with the base composition not containing any other surfactant other than said nonionic surfactant having said structure;
- c) a water-immiscible solvent which is a biocompatible monoester, diester or triester;
- d) ethanol; and

wherein ~~whereby~~ the relative concentration of the nonionic surfactant to propofol included in the base composition is not less than about three (3) parts of the nonionic surfactant to about one (1) part propofol, the relative concentration of the water-immiscible solvent to propofol is about three (3) to five (5) parts solvent to about ten (10) parts propofol, and the relative concentration of ethanol to propofol is about five (5) to six (6) parts ethanol to about ten (10) parts propofol.

Claim 85 (previously presented): The base composition of claim 84 in which the nonionic surfactant is selected from the group consisting of polyoxyethylene monoalkyl ethers, polyoxyethylene alkylphenols, polyethylene glycol fatty acid monoesters, polyethylene glycol glycerol fatty acid esters, polyoxyethylene sorbitan fatty acid esters, and polyoxyethylene sterols.

Claim 86 (previously presented): The base composition of claim 84 in which the nonionic surfactant is selected from the group consisting of *PEG-15 monolaurate*, *PEG-20 monolaurate*, *PEG-32 monolaurate*, *PEG-48 monolaurate*, *PEG-13 monooleate*, *PEG-15 monooleate*, *PEG-20 monooleate*, *PEG-32 monooleate*, *PEG-72 monooleate*, *PEG-15 monostearate*, *PEG-660 12-hydroxystearate*, *PEG-23 monostearate*, *PEG-40 monostearate*, *PEG-72 monostearate*, *PEG-20 glyceryl laurate*, *PEG-30 glyceryl laurate*, *PEG-20 glyceryl stearate*, *PEG-20 glyceryl oleate*, *PEG-30 glyceryl monooleate*, *PEG-30 glyceryl monolaurate*, *PEG-40 glyceryl monolaurate*, *PEG-20 sorbitan monooleate*, *PEG-20 sorbitan monolaurate*, *PEG-20 sorbitan monopalmitate*, and *PEG 20 sorbitan stearate*, *PEG-40 sorbitan monooleate*, *PEG-80 sorbitan monolaurate*, *POE-23 lauryl ether*, *POE-20 oleyl ether*, *PEG-30-60 nonyl phenol series*, *PEG-30-55 octyl phenol series*, and mixtures thereof.

Claim 87 (canceled)

Claim 88 (canceled)

Claim 89 (canceled)

Claim 90 (previously presented): The base composition of claim 84 in which the base composition is homogeneous.

Claim 91 (previously presented): The base composition of claim 84 in which the base composition is optically transparent.

Claim 92 (canceled)

Claim 93 (currently amended): The base composition as in claim ~~84~~ 92 in which the monoester is ethyl oleate, isopropyl myristate, ethyl laurate, butyl oleate, oleyl acetate, oleyl propionate, octyl octanoate, octyl decanoate, or oleyl oleate.

Claim 94 (withdrawn): The base composition as in claim 84 in which the water-immiscible solvent is a diester derived from a di-alcohol and a mono-acid.

Claim 95 (withdrawn): The base composition as in claim 94 in which the diester is propylene glycol dilaurate, propylene glycol dioleate, propylene glycol dicaprylate or 1, 2 butane glycol dioleate.

Claim 96 (withdrawn): The base composition as in claim 84 in which the water-immiscible solvent is a diester derived from a di-acid and a mono-alcohol.

Claim 97 (withdrawn): The base composition as in claim 96 in which the diester is dioleyl succinate, diethyl fumarate, diethyl malate, or diethyl adipate.

Claim 98 (withdrawn): The base composition as in claim 84 in which the water-immiscible solvent is a triester derived from an aliphatic acid and a trialcohol.

Claim 99 (withdrawn): The base composition as in claim 98 in which the triester is a triglyceride.

Claim 100 (withdrawn): The base composition as in claim 99 in which the triglyceride is glycerol tri-oleate or a medium chain triglyceride oil.

Claim 101 (withdrawn): The base composition as in claim 84 in which the water-immiscible solvent is a triester derived from an aliphatic tri-carboxylic acid and a mono-alcohol.

Claim 102 (withdrawn): The base composition as in claim 101 in which the triester is a triethyl citrate, tributyl citrate, or triethyl isocitrate.

Claim 103 (withdrawn): The base composition as in claim 84 in which the water-immiscible solvent is selected from the group of benzoic acid esters of ethanol, n-propanol, isopropanol, and benzyl alcohol.

Claim 104 (withdrawn-currently amended): The base composition of claim 84 that also comprises a physiologic carrier liquid that is isotonic to blood, thereby forming the microemulsion. ~~An intravenously injectable microemulsion for use as an anesthetic composition, comprising:~~

- ~~a) the base composition of claim 84; and~~
- ~~b) a physiologic carrier liquid which is isotonic to blood.~~

Claim 105 (withdrawn): The microemulsion of claim 104 in which the microemulsion is optically transparent.

Claim 106 (withdrawn): The microemulsion of claim 104 in which the concentration of the propofol is included in the microemulsion in an amount of up to about 5% by weight of the propofol to the volume of the microemulsion.

Claim 107 (withdrawn): The microemulsion of claim 104 in which the concentration of the propofol is included in the microemulsion in an amount of up to about 10% by weight of the propofol to the volume of the microemulsion.

Claim 108 (withdrawn): A method of preparing the self-microemulsifiable base composition as in claim 74, comprising the steps of:

a) measuring about eight or more parts of the nonionic surfactant to about one part of propofol and heating said nonionic surfactant to a preparation temperature above its melting point; and

b) combining the nonionic surfactant with a predetermined amount of propofol; thereby forming the base composition.

Claim 109 (withdrawn): A method of preparing the self-microemulsifiable base composition as in claim 84, comprising the steps of:

a) measuring about five parts of the nonionic surfactant to about one part of propofol and heating said nonionic surfactant to a preparation temperature above its melting point; and

b) combining the nonionic surfactant with predetermined amounts of water-immiscible solvent, ethanol and propofol; thereby forming the base composition.

Claim 110 (new): The base composition of claim 74 in which the propofol is not dissolved in oil.

Claim 111 (new): A self-microemulsifiable anhydrous base composition for use in the preparation of a spontaneously formed and thermodynamically stable microemulsion that can be used as an anesthetic composition, comprising:

a) liquid propofol; and

b) a nonionic surfactant consisting of polyoxyethylene (POE) having the structure of [POE(*n*)] sub $m$ -R'-R; where POE (*n*) is a polyoxyethylene moiety of *-mer* number *n*, and having *m* of these POE functional groups attached to R'; where the value of *m* is one to three; where R' is a linking moiety selected from glyceryl, sorbitan,

ester, amino, or ether functions; where R is a hydrophobic moiety consisting of saturated or unsaturated alkyl or alkylphenyl groups; and where the structure of the nonionic surfactant is further defined by a ratio of **A**, the total number of POE *-mer* units in the surfactant given by the product of *-mer* number **n** and total POE chain number **m** per molecule, to **B**, the number of carbons in the hydrophobic functional group R, the ratio of **A/B** being in the range of about 1 to 2 or in the range of about 0.7 to 4; and

wherein the nonionic surfactant is included in the base composition in a concentration of about eight (8) parts or more of the nonionic surfactant to one (1) part of propofol, with the base composition not containing any other surfactant other than said nonionic surfactant having said structure, and with the base composition not containing a co-solvent in an amount equal to or greater than about two (2) parts co-solvent to about one (1) part of the nonionic surfactant.

Claim 112 (new): A self-microemulsifiable anhydrous base composition for use in the preparation of a spontaneously formed and thermodynamically stable microemulsion that can be used as an anesthetic composition, comprising:

- a) liquid propofol;
- b) Solutol HS 15 as a nonionic surfactant; and

wherein the Solutol HS 15 is included in the base composition in a concentration of about eight (8) parts or more of the Solutol HS 15 to one (1) part of propofol, with the base composition not containing any other surfactant other than said SolutolHS 15, and with the base composition not containing a co-solvent other than naturally occurring contaminants present in Solutol HS 15.

Claim 113 (new): A self-microemulsifiable anhydrous base composition for use in the preparation of a spontaneously formed and thermodynamically stable microemulsion that can be used as an anesthetic composition, comprising:

- a) liquid propofol;
- b) Solutol HS 15 as a nonionic surfactant; and

wherein the Solutol HS 15 is included in the base composition in a concentration of about eight (8) parts or more of the Solutol HS 15 to one (1) part of propofol, with the



base composition not containing any other surfactant other than said Solutol HS 15, and with the base composition not containing a co-solvent in an amount equal to or greater than about two (2) parts co-solvent to about one (1) part of the Solutol HS 15.